IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

LEWIS WILLIAMS, JR., et al. Plaintiffs v. SMITH & NEPHEW, INC. Defendant	Case No. 1:14-cv-03138-CCB

OPPOSITION TO SMITH & NEPHEW'S MOTION TO DISMISS

Plaintiffs, Lewis and Angela Williams, by and through their attorneys, Daniel M. Clements, Gregory G. Hopper, and Salsbury, Clements, Bekman, Marder & Adkins, LLP, hereby file this Opposition to the Motion to Dismiss filed by Defendant, Smith & Nephew, Inc., and state as follows:

I. Introduction

Lewis Williams was admitted to the Greater Baltimore Medical Center in April 2013 with complaints of shortness of breath, fatigue, weakness, and other signs of cardiomyopathy. Testing revealed that a Birmingham Hip Resurfacing System implanted in his hip five years earlier had released significant amounts of Cobalt and other metal ions into his bloodstream, damaging and weakening his heart. The BHR System was surgically removed on July 9, 2013, and Mr. Williams' cardiomyopathy improved slightly. Unfortunately, his long-term exposure to cobalt and other metal ions had significantly and irreversibly damaged his heart and he is expected to suffer the consequences for the remainder of his life.

Following the lead of patients across the country, Mr. Williams and his wife, Angela Williams, filed the above-captioned products liability lawsuit against Smith & Nephew, the designer and manufacturer of the BHR System, to obtain compensation.

Smith & Nephew has filed a Motion to Dismiss. Misstating the Williams' claims and presenting arguments that have been rejected by Courts across the county, Smith & Nephew asserts that the Williams' negligence, strict liability, and breach of warranty claims are expressly and impliedly preempted and their Complaint is inadequately pled.

As outlined in more detail below, the Williams' claims are neither expressly nor impliedly preempted and contain sufficient factual matter to state a claim to relief that is plausible on its face. The Williams respectfully request that the Court deny the pending Motion and allow the case to go forward on its merits.

II. Relevant Background Information

A. The Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act

Congress passed the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act in 1976, after a number of high profile devices – pacemakers, Dalkon Shield intrauterine devices, and others – failed and caused thousands of reported injuries. See Carlos Rados, Medical Device and Radiological Health Regulations Come of Age, FDA Consumer, Jan./Feb. 2006, available at http://fda.gov. Congress intended the MDA to "swe[ep] back some state obligations and impose[ ] a regime of detailed federal oversight." Riegel v. Medtronic, Inc., 552 U.S. 312, 315-16 (2008).

The MDA created a regulatory framework that classified medical devices into three tiers: Class I, II, or III. Class I medical devices generally pose the lowest risk to the patient or user, Class II medical devices pose an intermediate risk, and Class III devices pose the highest risk.

Manufacturers of Class III medical devices are required to obtain premarket approval from the Food and Drug Administration before they can make their products available to patients or users. See 21 U.S.C. § 360(e). The premarket approval (PMA) process has been described as "rigorous" and the FDA cannot approve a medical device unless "it is reasonably assured the device is safe and effective." Riegel, 552 U.S. at 317.

B. Federal regulations and the ongoing post-PMA approval duties imposed on Class III medical device manufacturers

A manufacturer's obligation does not end once the FDA grants premarket approval. The MDA imposes a number of ongoing requirements, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order (21 C.F.R. § 814.80); "continu[e] [to] evaluat[e] and periodic[ly] report[ ] on the safety, effectiveness, and reliability of the device for its intended use" (§ 814.82(a)(2)); conducting ongoing, periodic batch testing (§ 814.82(a)(2)); implementing and conduct postmarket surveillance "to reveal unforeseen adverse events, the actual rate of anticipated adverse events, and other information necessary to protect the public health" (§ 822.2); and report and investigate any adverse events if it "receive[s] or become[s] aware of information, from any source, that reasonably suggests that a device . . . [m]ay

have caused or contributed to a death or serious injury or . . . [h]as malfunctioned . . . ." (21 U.S.C. § 803.50).

The MDA also requires manufacturers to comply with the FDA's Current Good Manufacturing Practice (CGMP) provisions – requirements that "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use" (21 C.F.R. § 820.1 and 820 et seq.). The CGMP requirements are discussed in more detail below.

While most changes to the labeling of an approved device require the FDA's prior approval, a manufacturer may make "[l]abeling changes that add to or strengthen a contraindication, warning, precaution, or information about an adverse reaction," "that add or strengthen an instruction that is intended to enhance the safe use of the device," or "that delete misleading, false, or unsupported indications." 21 C.F.R. 814.39(d)(1) and (d)(2)(i)-(iii). Those standards, and the associated process for a manufacturer to notify the FDA of "changes being effected" (CBE) to a device's labeling mirror the CBE provisions for brand name prescription drugs.

C. Smith & Nephew's Birmingham Hip Resurfacing System

Smith & Nephew's Birmingham Hip Resurfacing System is made-up of two components: a cemented femoral head component and a cementless, semi-hemispheric acetabular component. The BHR System is intended for use in patients who require hip surgery due to non-inflammatory arthritis or

inflammatory arthritis but who, due to their relatively younger age or increased activity level, may not be suitable for traditional total hip arthroplasty.

Smith & Nephew submitted a premarket approval (PMA) application for the BHR System to the FDA on July 19, 2004. Over the course of the next two years, it submitted 18 amendments. On May 9, 2006, Donna-Bea Tillman, Director of the FDA's Office of Device Evaluation, wrote a letter notifying Smith & Nephew that the BHR System had been given conditional approval and Smith & Nephew could begin commercial distribution of the device. A copy of the FDA Letter dated May 9, 2006 and the FDA's Conditions of Approval are attached hereto as **Exhibit 1**.

In its letter and Conditions of Approval, the FDA imposed a number of specific requirements on Smith & Nephew and its BHR System:

1. Smith & Nephew was only allowed to sell, distribute, and promote the BHR System for prescription use in accordance with 21 CFR 801.109 and § 520(e) of the Federal Food, Drug, and Cosmetic Act (FDA Letter at 2);

2. Smith & Nephew was only allowed to sell, distribute, or promote the BHR System for use in compliance with § 502(q) and (r) of the Federal Food, Drug, and Cosmetic Act (FDA Letter at 2);

3. Smith & Nephew was required to conduct a study of the longer-term safety and effectiveness of the BHR System in the United Kingdom based upon the experiences of the first 350 consecutive patients in the initial study (the Overall McMinn Cohort) reported in its application – Smith & Nephew was required to monitor and report the pain, function, movement, revision status, and adverse events experienced by these patients annually from the fifth year post-implantation (year five) to the tenth year post-implantation (year ten) (FDA Letter at 2);

4. Smith & Nephew was required to conduct a study of the longer-term safety and effectiveness of the BHR System in the United States based upon the experiences of 350 patients from up to 8 geographically and professionally diverse settings – Smith & Nephew was to monitor and report the clinical and radiographic data for each of the 350 patients annually from implantation (surgery, year 0) to the fifth year post-implantation (year five), send postcard questionnaires to each of the 350 patients and report their experiences annually from the sixth year post-implantation (year six) to the ninth year post-implantation (year nine), and monitor and report the clinical and radiological data for each of the 350 patients in the tenth year post-implantation (year ten (FDA Letter at 2));

5. Smith & Nephew was required to implement a training program including quarterly teleconferences or meetings for the first two years of the United States Study to provide clinical updates to investigators, discuss study issues including adverse events, and identify recommendations for the improvement of the training program and labeling and to report the findings of these conferences or meetings to the FDA (FDA Letter at 2);

6. Smith & Nephew was required to conduct a study on the learning curve and training program of doctors in the United States from up to 8 geographically and professionally diverse settings (academia, referrals, and community based sites) and to report annually on its findings (FDA Letter at 3);

7. Smith & Nephew was required to submit annual post-approval reports under 21 CFR 814.84 that included a bibliography and summary of unpublished reports of data from clinical investigations and nonclinical laboratory studies involving the BHR and reports in the scientific literature concerning the device (FDA Letter at 3 and Conditions of Approval at 2);

8. Smith & Nephew was required to submit adverse reaction and device defect reports to the FDA within 10 days after receiving or having knowledge of a mix-up of the device or its labeling, any adverse reactions, side effects, injury, toxicity, or sensitivity reactions attributable to the device; or any significant chemical, physical, or other change or deterioration in the device of any failure of the device to meet the specifications established in the approved PMA

that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling (Conditions of Approval at 2-3);

9. Smith & Nephew was required to submit a medical device report under the Medical Device Reporting (MDR) Regulation whenever it received or otherwise became aware of information that reasonably suggested that the BHR System may have caused or contributed to a death or serous injury or malfunctioned and a recurrence would be likely to cause or contribute to a death or serious injury (Conditions of Approval at 3-4);

10. Smith & Nephew was required to provide an analysis of adverse events and complaints related to the BHR System (Conditions of Approval at 2-3);

11. Smith & Nephew was required to issue a supplemental label that reflected the results of the post-approval studies, training program assessment, and adverse event analysis (Conditions of Approval at 2);

12. Smith & Nephew was required to submit a supplemental PMA when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitated a labeling, manufacturing, or device modification (Conditions of Approval at 1); and

13. Smith & Nephew was required to ensure that its "warranty statements [were] truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws" (FDA Letter at 3).

The FDA's letter referenced 21 C.F.R. 814.39(d), discussed in the previous section, and reminded Smith & Nephew that it did not have to wait to make certain types of labeling changes. See Conditional Approval Order at 1.

In addition to the specific requirements contained in the FDA letter and Conditions of Approval, Smith & Nephew was required to follow the FDA's

Current Good Manufacturing Practice (CGMP) provisions. See 21 C.F.R. § 820.1. Under these provisions, Smith & Nephew was required to:

1. establish and implement ongoing internal quality audits (§ 820.22);

2. establish and implement procedures to control the design of the device to ensure that it met specified design requirements;

3. establish and implement procedures for in-process and finished device acceptance to ensure that each production run, lot, and batch met established criteria (§ 820.30);

4. inspect and evaluate materials and components produced by suppliers (§ 820.50);

5. "control and monitor production processes to ensure that a device conforms to its specifications" (§ 820.70);

6. establish and implement procedures for in-process and finished device acceptance to ensure that each production run, lot, and batch met established criteria (§ 820.80);

7. "[a]nalyz[e] processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming products or other quality problems" (21 C.F.R. § 820.100);

8. establish and implement a program to conduct postmarket surveillance of its medical devices "to reveal unforeseen adverse events, the actual rate of anticipated adverse events, and other information necessary to protect the public health. (21 C.F.R. § 822.2); and

9. investigate and evaluate any adverse events involving death or serious bodily injury and to report them to the FDA within 30 days (21 U.S.C. § 803.50).

In its letter, the FDA warned Smith & Nephew that its failure to comply with any of the "postapproval requirement[s] constitutes a ground for withdrawal of approval of a PMA" and that "[c]ommercial distribution of a device that [was] not

in compliance with these conditions was a violation of the [Federal Food, Drug, and Cosmetic Act]." See FDA Letter at 4.

III. Standard of Review

The purpose of a motion to dismiss "'is to test the legal sufficiency of a complaint' and not to 'resolve contests surrounding the facts, the merits of a claim, or the applicability of defenses.'" Presley v. City of Charlottesville, 464 F.3d 480, 483 (4th Cir. 2006) (quoting Edwards v. City of Goldsboro, 178 F.3d 231, 243-44 (4th Cir. 1999)). To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcraft v. Iqbal, 556 U.S 662, 663 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The court must assume as true all well-pleaded facts set forth in the complaint, construing the allegations liberally and drawing all inferences in the light most favorable to the plaintiff. See Edwards, 178 F.3d at 244. A complaint does not need to provide detailed factual allegations, but instead must only "provide grounds of [the plaintiff's] entitlement to relief" with "more than labels and conclusions" or "a formulaic recitation of the elements of a cause of action." Twombly, 550 U.S. at 555. Stated differently, dismissal is only appropriate if a plaintiff's allegations, seen in the light most favorable to him, fail to "raise a right to relief above the speculative level" by pleading "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 545-47.

IV. Argument

A. The Williams' claims against Smith & Nephew are not expressly preempted by § 21 U.S.C. 360k.

1. The MDA preemption provision – § 21 U.S.C. 360k

The MDA contains an express preemption provision found at 21 U.S.C. § 360k. It provides as follows:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

2. The Supreme Court's discussion of express preemption under § 21 U.S.C. 360k.

The United States Supreme Court has addressed the scope of 21 U.S.C. § 360k(a) on two occasions. In Medtronic, Inc. v. Lohr, 518 U.S. 470, 481, 494-95 (1996), a plaintiff alleged that Medtronic pacemaker leads that had gone through the premarket notification process[1] malfunctioned and caused her to suffer an injury.

The Court began its analysis by noting two basic principles that govern preemption analysis. First, "because the States are independent sovereigns in our federal system . . . Congress does not cavalierly preempt state-law causes of

[1] The FDA's premarket notification process, also known as the "§ 510(k) process, is a short form route to approval for "predicate devices" – those that were already on the market when the MDA was passed in 1976 – of their "substantial equivalents." The § 510(k) process is less rigorous than the PMA process.

[2] The plaintiff in Gale either ignored or was unaware of the Supreme Court's

action." Id. at 485. And second, the purpose of Congress is the "ultimate touchstone in every preemption case." Id.

The Lohr Court was divided on the scope of the MDA's preemption clause. Justice Stevens, writing for himself and three other Justices, rejected Medtronic's argument that the MDA preempted all common law causes of action. They reasoned that Medtronic's construction of the provision would "have the perverse effect of granting complete immunity . . . to an entire industry that, in the judgment of Congress, needed more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use.'" Id. at 487. They noted that the MDA was passed to protect the pubic and nothing in its legislative history suggested that Congress feared the operation of the state common law system. See id.

Justice O'Connor, writing for herself and three other Justices, expressed a slightly different view. They explained that a state tort claims are "requirements" within the meaning of the MDA because they "operate to require manufacturers to comply with common law duties." Id. at 510 (O'Connor, J., concurring in part and dissenting in part). Unlike the Justices who joined Justice Stevens, these members of the Court believed that any common law duty that was different from or in addition to any requirement of federal law was preempted. With that said, these Justices concluded that the plaintiff's defective design claim was not preempted because the premarket notification process – dissimilar to the PMA process – only determined that the device was substantially equivalent to another device on the market, and therefore did not impose any "requirements" on the

device. The Justices explained that the plaintiff's manufacturing, labeling, and failure to warn claims were preempted to the extent that they sought to impose additional burdens on the manufacturer.

With eight Justices evenly divided into two camps, Justice Breyer charted a middle path and was the determining vote. He wrote that state tort claims should only be preempted when they conflicted with specific federal requirements applicable to a particular device. Id. at 504-08 (Breyer, J., concurring).

Despite their disagreement over the proper approach to take, the Justices unanimously rejected the argument that state tort law claims against the manufacturers of Class III medical devices that had successfully gone through the premarket notification process (§ 510(k) process) were expressly preempted. The Court held as follows:

> There is no suggestion in either the statutory scheme or the legislative history that the § 510(k) exemption process was intended to do anything other than maintain the status quo [which] included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design.

Id. at 494. Foreshadowing its later opinion, the Justices also explained that regardless of the approval process involved, state law tort claims would not be preempted if they mirrored the obligations imposed under federal law. The Court explained that nothing in the MDA denied states "the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." Id. at 495 (emphasis added).

In Riegel v. Medtronic, Inc., 552 U.S. 312, 317-20, 322-23 (2008), the Court took the reasoning in Lohr to the next logical step, holding that state law

tort claims against the manufacturers of Class III medical devices that had successfully gone through the FDA's full premarket approval (PMA) process were expressly preempted to the extent that they sought to impose different or greater obligations than federal law.

In Lohr and Riegel, the Supreme Court clearly held that claims based on violations of common law duties that run "parallel" to federal regulations are not preempted. In Lohr, the Court explained its holding as follows:

> Nothing in § 360k denie[s] [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of [state] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicated the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Lohr, 518 U.S. at 495. In Riegel, the Court was equally careful in its explanation, emphasizing that § 360k preemption only applied to claims that Class III medical devices "violated state tort law notwithstanding compliance with the relevant federal requirements." Riegel, 552 U.S. at 330 (emphasis added). The Court added that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id.

3. The Williams' negligence claim is not preempted by § 21 U.S.C. 360k.

In their Complaint, the Williams and their counsel made it very clear that they were not alleging that the FDA improperly approved the BHR System or that Smith & Nephew could be held liable if it complied with federal law. Instead, they explained that they were asserting parallel Maryland law claims based on violations of federal statutory and regulatory law.

a. Negligent manufacturing

The Williams allege that pursuant to 21 C.F.R. 814.80, Smith & Nephew, as the manufacturer of a Class III medical device, had a duty and was required to manufacture the BHR System implanted in Mr. Williams in a manner consistent with the conditions for approval specified by the FDA in the device's PMA approval order and any deviation from the approved specifications was a violation of federal law. See id. at ¶ 20.

The Williams' allege that Smith & Nephew violated this duty because Mr. Williams' BHR System was defectively manufactured and deviated from the approved specifications. They allege as follows:

> [T]he BHR System implanted in Mr. Williams had a different hardness in metal and a variance in other metallurgical properties that caused or allowed it to break down sooner and expose [Mr. Williams] to greater levels of cobalt and other metal ions in his bloodstream than what would have occurred had the System complied with the hardness and other specifications set forth in the original application, approved in the PMA approval order, and found in the Conditions of Approval.

Id. at ¶ 13.

In addition to holding Smith & Nephew responsible for negligently causing the defect, the Williams also seek to hold it responsible for failing to identify the issue in violation of federal regulations. Specifically, they allege that Smith & Nephew:

> 1. failed to establish and maintain adequate and thorough quality assurance and evaluative systems that, if they had been properly established and maintained, would have caused it to discover the defect as required by 21 C.F.R. 814.80, 814.82, and 814.84 and the FDA's Current Good Manufacturing Practice (CGMP) provisions (21 C.F.R. 820.22, 820.30, 820.70, 820.80, and 820.100) (¶ 28i);
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> 2. failed to establish and maintain adequate and thorough quality assurance and evaluative systems that, if they had been properly established and maintained, would have caused it to discover that the metal used in the BHR System implanted in other patients also had these defects as required by 21 C.F.R. 814.80, 814.82, and 814.84 and the FDA's Current Good Manufacturing Practice (CGMP) provisions (21 C.F.R. 820.22, 820.30, 820.70, 820.80, and 820.100) (¶ 28j); and
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> 3. failed to establish and maintain adequate and thorough processes, work operations, quality audit reports, quality records, service records, complaints, returned products, and other sources of quality data that would have identified nonconforming product and other quality problems including, but not limited to, that metal-on-metal components were wearing down and releasing cobalt and other metal ions into patients' bloodstreams, the incidence of cobalt and other metal poisoning in its patients were on the rise as were reports of symptoms caused by and associated with cobalt and other metal poisoning, the incidence of adverse events and complaints were greater than expected, anticipated, and reported in the PMA process, and that the metal used in the BHR System implanted in prior patients (patients who had a BHR System implanted before Mr. Williams had his BHR System implanted) had different hardnesses in metal and variances in other metallurgical properties that caused or allowed them to break down sooner and expose patients to greater levels of cobalt and other metal ions in his bloodstream than what would have occurred had the System

> complied with the hardness and other specifications set forth in the original application, approved in the PMA approval order and found in the Conditions of Approval as required by 21 C.F.R. 814.80, 814.82, and 814.84 and the FDA's Current Good Manufacturing Practice (CGMP) provisions (21 C.F.R. 820.22, 820.30, 820.70, 820.80, and 820.100) (¶ 28i).

The Williams allege that as a direct result of Smith & Nephew's actions, Mr. Williams was implanted with a defective and dangerous BHR System, it remained in place until it was removed on July 9, 2013, and "[t]hroughout this time, the BHR System released high levels of cobalt and other metal ions into Mr. Williams' bloodstream and caused him to develop metal poisoning, cardiomyopathy, heart damage, and other injuries." Id. at ¶ 33.

These allegations are perfectly appropriate and state a valid parallel claim under Lohr and Riegel because they are "premised on a violation of FDA regulations" and "the state duties . . . 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330.

b. Violations of other federal requirements

The Williams also allege that Smith & Nephew failed to comply with a number of other federal statutory and regulatory requirements. Specifically, that Smith & Nephew:

> 1. failed to conduct and report on a study of the longer-term safety and effectiveness of the BHR System in the United Kingdom based upon the experiences of the first 350 consecutive patients in the initial study (the Overall McMinn Cohort) and to adequately monitor and report the pain, function, movement, revision status, and adverse events experienced by these patients from the fifth year post-implantation (year five) to the tenth year post-implantation (year ten) as required by the May 9, 2006 FDA Letter (2) and 21 C.F.R. § 822.2 and 21 U.S.C. § 803.50 (¶ 28a);

2. failed to implement an adequate and proper training program for doctors who were implanting the BHR System in patients in the United States immediately after its approval including quarterly teleconferences or meetings for the first two years of the United States Study to provide clinical updates to investigators, discuss study issues including adverse events, and identify recommendations for the improvement of the training program and labeling as required by the FDA Letter (2) and 21 C.F.R. 814.82 and 814.84 (¶ 28b);

3. failed to implement an adequate and proper training program for doctors who were implanting the BHR System in patients in the United States after its approval so that they would have accurate and reasonable descriptions of the dangers associated with the failure of the BHR System, cobalt and metal ion poisoning, the need to monitor patients with high cobalt and metal ion levels in their blood, and the connection between cobalt and metal ion poisoning and harmful health effects like cardiomyopathy and other conditions as required by the FDA Letter (3) and 21 C.F.R. 814.82 and 814.84 (¶ 28c);

4. failed to adequately train the doctors in the United States who were implanting the BHR System in patients after its approval so that they would have accurate and reasonable about the potential dangers associated with cobalt and other metal poisoning, monitoring patients for cobalt and other metal poisoning, and recognizing the signs and symptoms associated with cobalt and other metal poisoning. In addition to minimizing the dangers presented as required by the Conditions of Approval and 21 C.F.R. 814.82 and 814.84 (¶ 28c);

5. failed to adequately investigate and report adverse events and complaints of patients who were experiencing pain, dysfunction, movement problems, revisions, and adverse events at a greater level than it predicted and was reporting to the FDA as required by the Conditions of Approval (2-3) and 21 C.F.R. § 822.2 and 21 U.S.C. § 803.50 (¶¶ 28a, 28e);

6. failed to adequately investigate and report adverse events and complaints of patients due to higher than anticipated wear and tear of their metal-on-metal components and highly elevated and unsafe levels of cobalt and metal ions in their

bloodstream and related physical issues including tissue infiltration, cardiac symptoms, pain, and other signs and symptoms associated with cobalt and metal ion poisoning as required by the Conditions of Approval (2-3) and 21 C.F.R. § 822.2 and 21 U.S.C. § 803.50 (¶¶ 28a, 28e);

7. failed to make timely reports about adverse events to the FDA and erroneously blamed the vast majority of the adverse events on non-product problems rather than BHR System malfunctions or defects in violation of the Conditions of Approval (2-3) and 21 C.F.R. § 822.2, 21 U.S.C. § 803.50, and 21 C.F.R. 814.82 and 814.84 (¶ 28e);

8. failed to adequately investigate adverse events and complaints by patients in the field – it only investigated and followed-up on a very small percentage (roughly 2%) of all field reported (patient reported) adverse events – in violation of the Conditions of Approval (2-3) and 21 C.F.R. § 822.2, 21 U.S.C. § 803.50, and 21 C.F.R. 814.82 and 814.84 (¶ 28e);

9. failed to issue PMA supplements, post-approval reports, Changes Being Effected label modifications (21 C.F.R. 814.29(d), detailed annual post-approval reports, or other information when it learned new information about the difficulties in implanting the BHR System, the potential for excessive wear and tear leading to cobalt and other metal ion release, differences in the levels of complications and problems between the patients in the original study and patients in the United States, and the scope of adverse events, complaints, and other issues involving the BHR System as required by the Conditions of Approval (2-3) and 21 C.F.R. § 822.2, 21 C.F.R. 814.29(d), 814.82 and 814.84 (¶ 28g);

10. failed to submit thorough and sufficiently detailed annual post-approval reports that included a bibliography and summary of unpublished reports of data from clinical investigations and nonclinical laboratory studies involving the BHR and reports in the scientific literature concerning the device as required by the Conditions of Approval and 21 C.F.R. 814.84 (¶ 28d);

11. failed to include information in its post-approval reports about the causal connection between the effects of high levels of cobalt and other metals in the blood stream and

> patient injury and about adverse events and other complaints that it was seeing in the field, both with its BHR System and other manufacturer's metal-on-metal hip replacement and resurfacing systems as required by the Conditions of Approval and 21 C.F.R. 814.84 (¶ 28d); and
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> 12. failed to stay production and sales of the BHR System while it conducted an investigation, initiate a voluntary recall, or inform the FDA when it learned new information about the difficulties in implanting the BHR System, the potential for excessive wear and tear leading to cobalt and other metal ion release, differences in the levels of complications and problems between the patients in the original study and patients in the United States, and the scope of adverse events, complaints, and other issues involving the BHR System as required by the Conditions of Approval and 21 C.F.R. § 822.2, 21 C.F.R. 814.29(d), 814.82 and 814.84 (¶ 28g).

The Williams allege that Smith & Nephew violated Maryland law when it violated these federal requirements. First, because "Maryland law treats violations of federal statutes and regulations as evidence of common law negligence and Smith & Nephew, as a manufacturer, seller, and distributor of products in Maryland, owed a common law duty to comply with all applicable laws and regulations." Id. at ¶ 27. Second, because "[i]n parallel with federal law, Maryland law imposed post-sale duties upon Smith & Nephew. It owed a common law duty to monitor the sale, development, and use of the BHR System, to discover defects or hazards associated with the use of the BHR System, warn . . . of these defects and hazards, and to take other actions to protect those exposed to these defects and hazards." Id. at ¶ 26.

There is a direct causal connection between these violations and Mr. Williams' injuries. As outlined in its letter and the Conditions of Approval, the FDA required Smith & Nephew to train and provide accurate information to the doctors

who were implanting the BHR System in patients in the United States, meaning there was a direct line of communication between Smith & Nephew and Mr. Williams' doctors. See FDA Letter (2).

The FDA also required Smith & Nephew to adequately investigate and report adverse events and complaints of patients who were experiencing pain, dysfunction, movement problems, revisions, and adverse events at a greater level than it predicted and had reported to the FDA. See Conditions of Approval (2-3); 21 C.F.R. § 822.2 and 21 U.S.C. § 803.50; and Pls' Compl. at ¶¶ 28a, 28e.

Had Smith & Nephew complied with its obligations and reported the true scope of the malfunction and cobalt and metal ion poisoning issue, the Williams allege, the FDA would have taken appropriate and timely action including, but not limited to, "changing the labeling for the BHR System, issuing warnings about cobalt and other metal poisoning, reviewing the full range of data to make decisions that would have prevented Mr. Williams and others from longstanding exposure to high levels of cobalt and other metals in their blood, ordering a halt in sales to conduct an impartial investigation into these issues, and/or ordering a recall of the BHR System." See Pls' Compl. at ¶ 29.

And, had Smith & Nephew complied with its obligations and reported the true scope of the malfunction and cobalt and metal ion poisoning issue, the Williams allege, "the doctors who treated Mr. Williams and the larger medical community would have known about the difficulties American doctors were having implanting the BHR System, the potential for excessive wear and tear leading to cobalt and other metal ion release and poisoning, the increased

number and frequency of adverse events, complaints, and complications being experienced in the United States, and the dangers patients were being exposed to and the injuries that were resulting as a result of the BHR System" and they would have taken action that would "greatly minimized the exposure Mr. Williams and other patients with implanted BHR System components had to cobalt and other metal ions and prevented him and them from suffering from metal poisoning, cardiomyopathy, heart damage, and other injuries." Id. at ¶ 30.

The Court should not be swayed by Smith & Nephew's attempt to mischaracterize the Wiliams' claims, stating that the Williams "ask[ ] this Court to impose an obligation to warn, to provide information on ion testing, that the FDA did not require." See Def's Mem. of Law at 11. The Williams simply allege that Smith & Nephew failed to comply with its post-PMA approval requirements and that its actions caused or contributed to Mr. Williams' injuries.

Again, these allegations are perfectly appropriate and state a valid parallel claim under Lohr and Riegel because they are "premised on a violation of FDA regulations" and "the state duties . . . 'parallel,' rather than add to, federal requirements." Riegel, 552 U.S. at 330.

4. The Williams' strict liability claim is not preempted by § 21 U.S.C. 360k.

The Williams allege that Smith & Nephew violated "federal regulatory and statutory law and Maryland common law" because "the BHR System at issue in this case deviated from the design and manufactur[ing specifications] approved by the FDA in its PMA approval order . . . ." See Pls' Compl. at ¶ 36. Specifically, that the BHR System at issue:

1. was designed and manufactured with a material hardness that was different and deviated from the material hardness identified in Smith & Nephew's PMA application and approved by the FDA in its approval order (¶¶ 36(a) and 36(b));

2. was manufactured with a material that could not withstand the foreseeable wear and tear forces and expected usage by patients for the amount of time identified in Smith & Nephew's PMA application and approved by the FDA in its approval order (¶ 36(d)); and

3. was designed and manufactured with a material composition and/or finish that was different and deviated from the material composition and/or finish identified in Smith & Nephew's PMA application and approved by the FDA in its approval order (¶¶ 36(e) and 36(f)).

The Williams allege that as a direct and proximate result of these defects, "the components wore down and released high levels of cobalt and other metal ions into [Mr. Williams'] bloodstream over a long period of time and caused him to develop metal poisoning, cardiomyopathy, heart damage, and other injuries." Id. at ¶ 37.

Smith & Nephew concedes that the Williams' manufacturing defect claim is not preempted by § 21 U.S.C. 360k. However, it argues that the design defect claim is preempted, characterizing the claim as stating that the BHR System "should have been designed in a manner other than that contemplated by its premarket approval." Def's Mem. of Law at 15.

The Williams do not dispute that a design defect claim would be preempted if the FDA approved the specific material composition and hardness requirements of the metal used in the BHR System at issue. At this stage in the proceedings, however, that information remains confidential and the Williams

have no way of knowing whether the FDA approved the specific material content and hardness of the metal or whether it gave more general guidelines and left this matter to Smith & Nephew. Until that information is available, the Williams contend that the Court does not have enough information to decide this issue.

5. The Williams' breach of warranty claim is not preempted by § 21 U.S.C. 360k.

The FDA Letter dated May 9, 2006 warned Smith & Nephew that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws." See FDA Letter at 3.

The Williams allege that when "Mr. Williams agreed to have the BHR System implanted, and throughout time Mr. Williams' BHR System was in place, Smith & Nephew, directly and by and through its sales representatives who worked with Mr. Williams' doctor and interacted with Mr. Williams, repeatedly warranted, both expressly and impliedly, that the BHR System was . . . free from known or knowable defects and hazards." Id. at ¶ 37. They further allege that Smith & Nephew's sales materials and brochures contained numerous references to the BHR Systems' effectiveness and safety and durability, specifically stating their hip system "did not experience the same wear and tear problems that other hip replacement and resurfacing systems were experiencing and that it was made through a manufacturing process that prevented cobalt and other metal ion release." Id.

Smith & Nephew assert that the Williams "challenge[ ] the FDA's finding that the device was (and is) safe and effective, as well as the design the FDA approved." Def's Mem. of Law at 14-15.

This is simply not the case. The Williams' breach of warranty claim challenges the specific representations made, namely that the BHR System was not safer than the other hip replacement/resurfacing systems on the market, the BHR System experienced the same types of wear and tear problems that other hip replacement/resurfacing systems experienced, and the manufacturing process used to make the BHR System components did not prevent cobalt and other metal ion release. These representations were outside of the PMA approval process, were not decided or authorized by the FDA, and do not challenge the FDA's approval of the BHR System.

6. U.S. District Courts have rejected the express preemption arguments made by Smith & Nephew in this case

Several U.S. District Courts have rejected the express preemption arguments made by Smith & Nephew.

a. Comella v. Smith & Nephew

In Comella v. Smith & Nephew, Inc., 2013 WL 6504427 (N.D. Ill. 2013), attached as **Exhibit 2**, the United States District Court for the Northern District of Illinois denied a motion to dismiss nearly identical to the one made in this case. The plaintiff, a woman with a Birmingham Hip Replacement system, filed negligence and strict products liability claims against Smith & Nephew. She alleged that Smith & Nephew "breached a common law duty by failing to advise the FDA about dangers that became manifest after the product was put on the market" and breached a common law duty by "violat[ing] the Act and CGMPs under various provisions of 21 CFR § 820 [including] Defendant's [delayed] handling of over six hundred Adverse Events Reports" and "fail[ure] to make

complete and accurate post-market reports." Id. at 4. She claimed that "had [Smith & Nephew] complied with the federal regulations, the dangers of the product would have been disseminated, [her] doctor would not have recommended the BHR System to [her], and [she] would not have suffered the injuries caused by the BHR System." Id. The plaintiff also alleged that "the particular [hip replacement system] . . . was defective and unreasonably dangerous because [Smith & Nephew] failed to adhere to the approved design." Id. at 3.

In its motion, Smith & Nephew argued, like it argues here, that the plaintiff's state-law negligence and strict liability claims based on a "fail[ure] to advise the FDA about dangers that became manifest after the product was put on the market" imposed a requirement that was 'in addition to' federal requirements and, thus, was expressly preempted." Id. at 2.

The Comella Court rejected Smith & Nephew's express preemption argument. Citing the Supreme Court's findings in Lohr and Riegel, the Court explained that "[a] claim . . . based on a state common law duty that is sufficiently parallel to the requirement under . . . federal regulations imposes no additional obligation and is not preempted." Id. After going through the plaintiff's allegations, the Court held that Smith & Nephew's federal obligations to warn the FDA about dangers after the BHR system left its hands and its common-law post-sale duty to warn were "sufficiently parallel" to not be preempted. Id.

While Smith & Nephew asserts that Comella was "inconsistent with Buckman and Medtronic," it does not explain its position or challenge the Comella Court's reasoning in any way. Def's Mem. of Law. at 13 fn. 4.

b. Elmore v. Smith & Nephew

In Elmore v. Smith & Nephew, Inc., 2013 WL 1707956 (N.D. Ill. 2013), attached as **Exhibit 3**, the United States District Court for the Northern District of Illinois denied a motion to dismiss nearly identical to the one presented in this case. The plaintiff, a woman with a Birmingham Hip Replacement system, filed negligence and strict products liability claims against Smith & Nephew. Her claims were "based on numerous violations of [the FDA's Current Good Manufacturing Processes (CGMPs)], including defendant's failure to comply with design controls under 21 CFR § 820.30, failure to inspect and verify products under 21 CFR § 820.80, and failure to take appropriate corrective and preventative actions under 21 CFR § 820.100." Id. at 1. She claimed that had Smith & Nephew complied with these regulations, the dangers of the product would have become known and her doctors would have taken action to protect her from harm.

In its motion, Smith & Nephew argued that the plaintiff's state-law negligence and strict liability claims should be dismissed because "[o]nce a medical device has cleared the FDA's stringent [premarket approval (PMA)] process . . . a plaintiff cannot attack the design of the device under tort law." Id. at 2. It also argued, like it argues here, that "[b]asing state-law negligence claims on [the FDA's CGMPs] is an attack on the PMA process itself . . . ." Id.

The Elmore Court rejected Smith & Nephew's express preemption arguments. It held that Smith & Nephew had an ongoing, post-PMA approval duty to comply with the FDA's CGMP requirements. Citing cases from the United States Courts of Appeals for the Sixth and Seventh Circuits that upheld state-law negligence claims, the Court explained that medical device manufacturers are required to adhere to CGMPs even after their products receive PMA approval. See id. (citing Howard v. Sulzer Orthopedics, Inc., 382 F.App'x 436, 441 (6th Cir. 2010) and Bausch v. Stryker Corp., 630 F.3d 546, 556 (7th Cir. 2010)). Citing a Congressional Research Service report, the Court also explained that "even after a medical device has received pre-market approval, 'manufacturers . . . [still] must comply with various regulations on labeling and advertising, manufacturing, postmarketing surveillance, device tracking, and adverse event reporting.'" Id. (quoting Judith A. Johnson, Cong. Research Serv., R421130, FDA Regulation of Medical Devices 12 (2012)). The Court also explained that "[b]ecause plaintiff's common-law claims [were] based on alleged violations of federal law, they impose[d] no requirement 'different from, or in addition to' the requirements of the federal regulations . . . ." Id.

c. Gale v. Smith & Nephew

In Gale v. Smith & Nephew, Inc., 989 F.Supp.2d 243 (S.D.N.Y. 2013), the plaintiff, a man with a Birmingham Hip Replacement System, filed negligence, products liability, and breach of warranty claims against Smith & Nephew. The plaintiff's complaint was not a model of proper pleading. Though the Court held

that a number of the plaintiff's claims were preempted,[2] it allowed the plaintiff's fifth claim – that after Smith & Nephew obtained PMA approval it failed to monitor patients' blood levels for dangerous levels of metal ions, warn doctors when it learned that patients were developing organ damage, and report adverse events to the FDA – to stand. See id. at 251. The Court noted that unlike a generic failure to warn claim, the plaintiff was essentially alleging that Smith & Nephew failed to comply with the monitoring and reporting requirements imposed by the FDA as a condition for approving the device. The Court explained that this claim was not preempted because it "successfully thread[ed] the needle between Riegel and Buckman; it [was] a state-law tort claim based on an alleged violation of a specific premarket approval requirement, and it link[ed] the federal violation to plaintiff's injuries." Id.

d. Herron v. Smith & Nephew

In Herron v. Smith & Nephew, Inc., 2014 WL 1232224 (E.D.Ca. 2014), attached as **Exhibit 4**, the plaintiff filed state-law negligence and strict liability claims against Smith & Nephew alleging that a BHR System implanted in his body leaked cobalt ions and caused him to experience ongoing pain and suffering. In response, Smith & Nephew filed a motion asking the U.S. District Court for the Eastern District of California to dismiss the plaintiff's claims on preemption grounds.

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[2] The plaintiff in Gale either ignored or was unaware of the Supreme Court's opinions in Lohr and Riegel. He alleged that the BHR System "contained a design and/or manufacturing defect" without "so much as referenc[ing] the FDA, federal law, or federal regulation[s]." Id. at 249. The Gale Court rightfully held that this claim, without more, was preempted.

In reviewing the plaintiff's Complaint in Herron, the Court noted that "some portion of [the plaintiff's claims were] not preempted because they [were] based upon state claims that parallel the federal requirements of the MDA and its implementing regulations." Id. at 8. For example, the plaintiff alleged that the BHR "was designed and/or manufactured in violation of the Act and regulations promulgated pursuant to it." Id. at 7. The Court explained that if the plaintiff meant that the device, as approved, was defective, then the plaintiff's claim was preempted. See id. On the other hand, if the plaintiff meant "that the device he received (and was implanted in him) differed in design and manufacture from the device that received premarket approval, and that the design and manufacture of the device he received was made in violation of the Act, then there [was] no preemption [because he was] alleging a parallel claim . . . ." Id.

The plaintiff also alleged that Smith & Nephew failed to appropriately respond to adverse incident reports, failed to investigate returned BHR components, and continued to sell BHR Systems when it knew or should have known that they were malfunctioning. The Court explained that these allegations likely applied to post-PMA approval conduct, and thus were not subject to preemption, but that they "could be clearer, by expressly specifying that they refer to post-PMA activities." Id.

While the Herron Court ultimately granted Smith & Nephew's motion, it did so because the complaint was inartfully written and it wanted the plaintiff to make it clear whether he was "taking issue with the results of the PMA process, in which case [his claims were] preempted, or he [was] taking issue with how [Smith

& Nephew] carried out [its] PMA-imposed responsibilities, in which case they [were] not preempted." Id. at 8.

e. Tillman v. Smith & Nephew

In Tillman v. Smith & Nephew, 2013 WL 3776973 (N.D.Ill. 2013), attached as **Exhibit 5**, the United States District Court for the Northern District of Illinois denied Smith & Nephew's motion to dismiss on preemption grounds. The plaintiff, a man with a BHR System, filed negligence and strict liability claims against Smith & Nephew based on violations of its duty to comply with design controls under 21 C.F.R. § 820.30, failure to inspect and maintain in-process and final device acceptance activities under 21 C.F.R. § 820.80, failure to implement corrective and preventative actions under 21 C.F.R. § 820.100, and failure to investigate complaints under 21 C.F.R. § 820.198. See id. at 3. The Court explained that "[b]ecause [the plaintiff's] claims are based on alleged violations of the FDA's CGMPs, they [did] not impose any additional or different requirements from federal ones and [were] thus not expressly preempted." Id.

f. Frederick v. Smith & Nephew

In Frederick v. Smith & Nephew, Inc., 2013 WL 6275644 (N.D. Ohio 2013), attached as **Exhibit 6**, the United States District Court for the Northern District of Ohio denied a motion to dismiss nearly identical to the one presented in this case, though on slightly different grounds than the Courts cited above. In that case, the plaintiff, a man with a BHR System, filed negligence and strict products liability claims against Smith & Nephew asserting that the BHR System "was defectively designed, [Smith & Nephew] failed to adequately warn of the

design defect of which it was aware, and [Smith & Nephew] breached its express and implied warranties that the device was safe and reliable . . . ." Id. at 1.

In it Motion, Smith & Nephew argued that the plaintiff's claims should be dismissed because "the state laws under which [the] claims [were] brought impose[d] different or additional requirements on the device at issue than was imposed by the FDA." Id. at 2.

The Frederick Court explained that "claims premised on a violation of FDA regulations or requirements are 'parallel' claims and do not impose requirements that are different from or in addition to federal requirements, and may not be preempted by the MDA." Id. Rather than reach the merits of the Motion, however, the Court noted that the parties had not conducted sufficient discovery about "the specific details, extent and scope of the federal requirements and/or regulations imposed by the PMA" for the record to be "fully developed." Id. at 3. Until all of the federal requirements were fully discovered, in explained, "it is premature to conclude that plaintiff's claims [were] subject to preemption under the MDA." Id.

These opinions are consistent with the opinions of other courts that have rejecting express preemption arguments. See Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997) (finding that a claim that a Class III medical device was manufactured in violation of "FDA requirements and agreed-upon procedures," causing it to contain "metallurgical defects" that made it weaker and more prone to developing "stress cracks under reasonably expected forces," adequately stated a "parallel claim" and was not expressly preempted); Bass v. Stryker Corp., 669 F.3d 501, 510 (5th Cir. 2012) (reversing a trial court's

dismissal of a negligence and strict liability claim against the maker of a hip replacement system and noting that "if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the [FDA's listing of Current Good Manufacturing Processes] and that this failure caused the injury, the plaintiff will have pleaded a parallel claim."); Hofts v. Howmedica Osteonics Corp., 597 F.Supp.2d 830, 836 (S.D. Ind. 2009) (denying a motion to dismiss on preemption grounds where the plaintiff, a man with a malfunctioning Trident Ceramic Acetabular System (artificial hip), alleged that "the manufacturing process for the Trident and certain of its components did not satisfy the FDA's PMA standards for the devices," the Trident implanted in him "had an impurity, imperfection, and/or another product defect [that] deviat[ed] from [Howmedica's] design and quality manufacturing standards for the Trident approved by the FDA," and Howmedica failed to exercise reasonable care and/or was reckless in the testing, manufacture, quality assurance, and sale of the implanted Trident."); and In re St. Jude Medical, Inc. Silzone Heart Valves Products Liability Litigation, 2004 WL 45503, 11 fn. 13 (D.Minn. 2004) (denying a motion to dismiss on express preemption grounds where the plaintiff, a man who had been injured when his heart valve failed, alleged that the defendant manufacturer knew that a lab animal with the heart valve had died during testing and doctors were reporting "high rates of stroke and other thromboembolic events" in the field during both the "pre-approval and post-approval periods" and "did not report the problems to the FDA.").

B. The Williams' claims against Smith & Nephew are not impliedly preempted.

In Buckman Co v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001), a group of plaintiffs sued the maker of an orthopedic bone screw alleging that it made fraudulent representations to the FDA in order to obtain premarket approval for its device. The Supreme Court declined to address whether express preemption applied, instead holding that "fraud of the FDA" claims were impliedly preempted. Id. at 350. The Court noted that the FDA was charged with policing fraud on it and had a variety of enforcement options that allowe[ed] it to make "a measured response to suspected fraud." Id. It reasoned that permitting state-law claims alleging that a defendant defrauded the FDA would conflict with the FDA's responsibility to police fraud consistent with its judgment and objectives. See id.

In this case, the Williams are not claiming that Smith & Nephew made fraudulent representations to the FDA in order to obtain approval for the BHR System – a "fraud on the FDA" claim. They are also not asserting that Smith & Nephew had an obligation to warn Mr. Williams or his doctors of dangers outside of the process created by the post-PMA approval regulations. As such, Buckman simply does not apply.

In Bass v. Stryker Corp., 669 F.3d 501, 514 (5th Cir. 2012), the Fifth Circuit explained that "there is a difference between the 'freestanding federal cause of action based on violation of the FDA's regulations' presented by the plaintiffs in Buckman and a state-law tort claim." It also noted that Riegel, which was decided long after Buckman, unequivocally held that parallel state claims survive preemption analysis. See id.

This is not the first time Smith & Nephew has made its implied preemption argument in a BHR System case. In Comella, for example, it made the argument and the United States District Court for the Northern District of Illinois denied it because the plaintiff's allegations, virtually identical to those in this case, were "capable of existing independent of [federal] regulations as a failure of the duty to warn." Comella, 2013 WL 6504427 at 2. Likewise, in Elmore, the Court explained that state-law tort claims of this type "do not conflict with the primary objective of the FDA's regulatory scheme – ensuring the safety and effectiveness of medical devices. Rather, plaintiffs' negligence and strict liability claims are based on the breach of well-recognized duties already owed under state law." Elmore, 2013 WL 1707956 at 4. And, in Gale, the United States District Court for the Southern District of New York denied Smith & Nephew's motion because the plaintiff's failure to warn claim was based on the specific requirements in the FDA premarket approval's monitoring and reporting requirements. Gale, 989 F.Supp.2d 243, 251 (S.D.N.Y. 2013).

Smith & Nephew's citation to Bausch v. Stryker Corp., 630 F.3d 546, 556-57 (7th Cir. 2010) does not help it. In that case, the Seventh Circuit rejected a manufacturer's argument that implied preemption is necessary to maintain the statutory and regulatory framework under which the FDA pursues difficult and often competing objectives for medical devices. While recognizing that fraud-on-the-agency claims may be impliedly preempted because the FDA has the exclusive power to deter and punish fraud, the Court explained that state law design and manufacturing defect claims are part of "the historic police powers of

the States [and are] not . . . superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Id.

C. The Williams' Complaint is sufficient under Federal Rule of Civil Procedure 8.

1. Sufficiency

Rule 8(a)(2) requires a complaint to contain a "short and plain statement of the claim showing that the pleading is entitled to relief." Fed.R.Civ.P. 8(a)(2). A complaint must do more than simply assert "labels and conclusions" and "a formalistic recitation of the elements of a cause of action." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). Instead, it must give the defendant fair notice of what the claim is about and the grounds upon which it rests and establish a "reasonably founded hope that that the discovery process will reveal relevant evidence to support [a] claim." Id. at 559. "[A] plaintiff's pleading burden corresponds to the amount of information available." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

In its Motion, Smith & Nephew asks the Court to extend Twombly and Iqbal well beyond where they have been taken before, essentially arguing that the Williams were not just required to establish a plausible claim, they were required to prove every allegation made in their initial pleading. Not coincidentally, Smith & Nephew makes these arguments knowing that most of the product-specific information it claims is required is kept confidential by federal law and can only be made available during discovery.

Contrary to Smith & Nephew's argument, the Williams' allegations in this case contain substantial factual detail and are not simply labels and conclusions

or a formalistic recitation of the elements of a cause of action. They not only give it fair notice of what the claim is about, but also demonstrate that the Williams are making plausible claims.

For example, the Williams allege that the BHR System at issue was defectively manufactured and Smith & Nephew failed to catch the problem before it was released onto the market. They allege that the metal used was too soft and it wore down over time, causing cobalt and metal ions to be released into Mr. Williams' bloodstream and caused him to develop metal poisoning and cardiomyopathy. This claim is plausible on its face.

The Williams also allege that Smith & Nephew failed to investigate or follow-up on 98% of the adverse events of which it was made aware. While Smith & Nephew argues that the FDA never recalled or took action to limit the distribution of the BHR System after the PMA application was approved, this allegation explains why the FDA did not act (post-PMA approval, not in granting the PMA in the first place) and demonstrates why Mr. Williams' doctor and others were slow to be concerned about cobalt and other metal ion poisoning. This claim is plausible on its face.

The Williams further allege that Smith & Nephew became aware during the post-PMA approval period that BHR Systems were wearing excessively and causing cobalt and other metal ions to release into patients bodies and they did not issue PMA supplements, post-approval reports, Changes Being Effected label modifications (21 C.F.R. 814.29(d), or other information as required or allowed by federal law. They allege that Smith & Nephew's failure prevented Mr.

Williams' doctor and the medical community from understanding the scope of the problem and taking action to protect Mr. Williams and other patients. This claim is plausible on its face.

The Williams also allege that when "Mr. Williams agreed to have the BHR System implanted, and throughout time Mr. Williams' BHR System was in place, Smith & Nephew, directly and by and through its sales representatives who worked with Mr. Williams' doctor and interacted with Mr. Williams, repeatedly warranted, both expressly and impliedly, that the BHR System was . . . free from known or knowable defects and hazards." Id. at ¶ 37. They further allege that Smith & Nephew's sales materials and brochures contained numerous references to the BHR Systems' effectiveness and safety and durability, specifically stating their hip system "did not experience the same wear and tear problems that other hip replacement and resurfacing systems were experiencing and that it was made through a manufacturing process that prevented cobalt and other metal ion release." Id. They allege that Mr. Williams relied on these statements and was injured as a result. This claim is plausible on its face.

The level of factual specificity in the Williams' Complaint goes well beyond what courts have approved in other cases. In Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010), for example, the Seventh Circuit reviewed a complaint failed to identify the alleged defect or the specific federal regulatory requirements that were alleged to be violated. Rejecting the manufacturer's arguments under Twombly and Iqbal, the Court explained that while the addition of those details would make the complaint stronger, "[it did] not believe the absence of those

details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6)." The Court explained that "[t]here are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular. The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new plausibility standard applied in Iqbal and Twombly." The Court also offered the following suggestion:

> In applying that standard to claims for defective manufacture of a medical device in violation of federal law . . . district courts must keep in mind that much of the product specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.

Id. at 558.

It is also worth noting that a number of courts have rejected the pleading insufficiency arguments advanced by Smith & Nephew in this case. In Elmore and Tillman, for example, the plaintiffs simply alleged that the BHR System was defective, Smith & Nephew failed to properly respond to adverse incident reports, and they suffered injuries. In both cases, courts held that while additional allegations would strengthen their claims, they were sufficient under the circumstances because they suggested a link between the BHR System and the plaintiff's injuries.

2. An opportunity to amend

If the Court were to find that the Williams' Complaint was improperly pled or insufficient in some respect, they ask that it afford them an opportunity, after

reviewing the Court's opinion, to amend and correct the error. See Bausch v. Stryker Corp., 630 F.3d 546, 549, 562 (7th Cir. 2010) (finding that a trial court's refusal to allow the plaintiff's to amend a claim against the manufacturer of a hip replacement system was an abuse of its discretion).

V. Conclusion

WHEREFORE, and for the foregoing reasons, Plaintiffs, Lewis and Angela Williams, respectfully request that the Motion to Dismiss filed by Defendant, Smith & Nephew, Inc., be denied.

_____/s_____
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